

TFW

PATENT

1614



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Re: Patent application of
Mortimer Civan et al.

Serial No.: **10/009,581**

Filed: **April 30, 2002**

For: **Methods for Controlling IntraOcular Pressure**

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: **Group Art Unit: 1614**
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: **Examiner: Donna Jagoe**
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: **Conf. No. 1751**
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**CERTIFICATE OF MAILING
UNDER 37 C.F.R. 1.8(a)**

I hereby certify that this paper, along with any paper referred to as being attached or enclosed, is being deposited with the United States Postal Service on the date indicated below, with sufficient postage, as first class mail, in an envelope addressed to: Mail Stop Amendment; Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

BY Brenda Matraji

DATE: July 14, 2006

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

RESPONSE

Sir:

The Office is thanked for the opportunity to correct the election in response to the Restriction Requirement mailed February 21, 2006, although we are still somewhat confused by the Examiner's requirement. We will certainly try to comply with the requirements. However, if we still have not made the requisite election, it is hoped that correction can be further made by telephone with Applicants' undersigned representative to avoid further delay. We are happy to comply with the Office, but we must first have an understanding of what is being required with regard to the present invention.

The Examiner has separated species A-E, saying that the species lack unity. Consequently, in the Response dated March 21, 2006, Applicants elected species A, and asked that it be combined with Species B, since no additional search is required. The invention encompasses one - and only one concept - that is, the lowering of intraocular pressure (IOP) by applying NHE inhibitors, comprising selective NHE-1 inhibitors and non-selective inhibitors of the general class of NHE exchangers.

However, the Examiner's request that Applicants elect one representative agent from each of species A-E, is entirely puzzling. In light of the foregoing years of prosecution for this application, claims encompassing species C, D and E are not currently in prosecution (a decision made in response to earlier Office Actions to move the case to allowance). Thus, the Applicants' present application claims only species A and species B, to which Applicants respond as follows:

<u>Species</u>	<u>Representative Agent</u>	<u>Pending Claims</u>
A. NHE inhibitors	includes selective NHE-1 inhibitors, such as EIPA (ethyl-isopropyl-amiloride) and non-selective inhibitors, such as amiloride	94-116
B. NHE 1 inhibitors	includes selective NHE-1 inhibitors, such as ethyl-isopropyl-amiloride	94-96, 99-110

Applicants are reluctant to provide representative agents at this time for species C-E, since those species are not in prosecution, and there is concern that by providing such information the situation will be made unnecessarily complex. Nevertheless, since Applicants are required to provide a full and complete response, and since the information was requested by the Examiner, Applicants respond as follows for species C-E:

<u>Species</u>	<u>Representative Agent</u>	<u>Pending Claims</u>
C. $\text{Na}^+ - \text{K}^+ 2\text{Cl}^-$ symport inhibitors	See specification pgs. 14-15 anions, e.g., bumetanide	94, 97-98, 102-105, 108-110, 115-116
D. AE2 inhibitors	See specification pgs. 15-16, 4,4'-diisothiocyanatostilbene- 2,2'-disulfonic acid (DIDS)	94, 99-100, 102-114
E. miotics, beta blockers carbonic anhydrase inhibitors and precursor prostaglandins	See Example 3; pilocarpine, timolol, acetazolamide and latanoprost, respectively carbonic anhydrase inhibitors and precursor prostaglandins	94, 100-114

If the foregoing response is not what the Examiner is seeking, it is respectfully suggested that there is a basic misinterpretation of what Applicants intended by their invention. As presently claimed, Applicants' invention is directed to the regulation of IOP in the eye by administering to the eye a pharmaceutical composition comprising a pressure-modulating amount of a sodium-hydrogen exchanger (NHE) inhibitor. Therefore, the invention does not present multiple species, but rather – only one species – an NHE inhibitor. Thus, species A represents all pending claims. The remaining claims define subsets of NHE inhibitors within Applicants' invention, but each is still an NHE-inhibitor. See, Declaration of Dr. Civan, filed with the Response of November 10, 2005. Notably in the Declaration, the invention is defined as administering a pressure-modulating amount of a NHE inhibitor, and that in the cited art, neither timolol nor any other beta blocker is considered to be an NHE inhibitor. Nevertheless, Applicants have made their best effort to respond, although it does seem to lead to a circular argument.

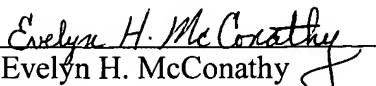
Presently the case is stalled and either the Office does not understand the invention or Applicants have failed to teach what otherwise seems to be a very clear and important invention. Unfortunately, this impasse has resulted in significant losses of time and resources by all involved, and a loss of this important invention to the public. If we have not adequately answered the species request, perhaps an interview would prove helpful with the inventor and inventors' representative to move this case forward. To this effect the Examiner is thanked for her understanding and cooperation.

Applicants again select species B (NHE-1) inhibitors, such as selective NHE-1 inhibitors, including ethyl-isopropyl-amiloride and derivatives.

Applicants' undersigned attorney may be reached by telephone at (215) 988-3361. All correspondence should be directed to the below-listed address.

Respectfully submitted,

Date: July 14, 2006


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